

Docket No.: 085742-0496

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Zhengming CHEN

Patent Number: 7,202,259

Application No.: 10/714,066

Filed: November 11, 2003

For: THERAPEUTIC AGENTS USEFUL FOR TREATING PAIN

PETITION UNDER 37 CFR 1.183

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Under 37 CFR 1.183, on petition of the interested party, the Director or the Director's designee may suspend or waive, in an extraordinary situation and when justice requires, any requirement of the regulations which is not a requirement of the statutes. This Petition Under 37 CFR 1.183 requests the Director suspend or waive any requirements of the regulations so that the Director may reset the date of the Patent Term Adjustment Determination by the U.S. Patent and Trademark Office ("PTO") to make timely a request for reconsideration of the patent term adjustment calculation for U.S. Patent No. 7,202,259, filed as Application No. 10/714,066 on November 11, 2003 and issued on April 10, 2007.

This Petition under 37 CFR 1.183 also requests the Director to take any other actions that will permit the reconsideration of the Patent Term Adjustment for this patent to accommodate recalculation under the terms of *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010).

This patent falls into a category of patents entitled to additional patent term adjustment (PTA) with no regulation to provide for the granting of such PTA. This petition is accompanied by the \$400 fee set forth in 37 CFR 1.17(f).

This Petition seeks correction of an extraordinary and unjust situation arising out the patent regulations. The '259 patent is entitled to PTA of 498 days under a correct interpretation of 35 U.S.C. § 154 and in accordance with *Wyeth*. The PTO granted only 350 days using a calculation that was only recently determined to be incorrect in *Wyeth*. The PTO decided not to appeal the *Wyeth* decision. It is extraordinary and unjust to deprive the instant patent of the valuable patent term adjustment it is due under the statute.

The U.S. Patent & Trademark Office ("PTO") permits a Request for Recalculation of Patent Term Adjustment in View of *Wyeth* (PTO/SB/131) for patents issued before March 2, 2010 that were not issued more than 180 days before the Request was filed. The instant patent does not fall within this time period restriction.

The arbitrary date restrictions for PTA recalculation of patents falling victim to the PTO's old, pre-*Wyeth* calculation deprives patents falling outside of the date requirements for filing a Form PTO/SB/131 of a means to obtain the valuable patent term adjustment due them. PTA under 35 U.S.C. § 154 is in effect for applications filed after May 29, 2000. The instant patent was filed after this date. It is unjust, but correctable under this Petition, to deprive the patent of its due PTA under the statute, particularly since the PTO has voluntarily changed the way it makes the calculation. Any delay or need for patent term adjustment is not the fault of the patentee.

Summary of Patent Term Adjustment under 35 U.S.C. § 154

35 U.S.C. § 154 guarantees that the PTO will provide at least one notification under section 132 or a notice of allowance not later than 14 months after the date on which the application was filed, and subsequent notifications within four months of an applicant's response. PTO delays beyond these times are referred to as "A" delays.

35 U.S.C. § 154 further guarantees a no more than 3-year application pendency. This does not include time consumed by continued examination requested by the applicant. PTO delays beyond this 3-year period are referred to as "B" delays. PTO delays do not include "overlap" under 35 U.S.C. § 154(b)(2)(A). Applicant delay is deducted from the PTO delay to arrive at the PTA.

PTO Practice Prior to *Wyeth*

Prior to the Federal Circuit's holding in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), the PTO interpreted "no overlap" under 35 U.S.C. § 154 to mean that any A delay would necessarily result in B delay. Thus, an applicant was entitled to a PTA equal to the greater of the two types of delay, but not both.

The Correct Calculation under *Wyeth*

In *Wyeth*, the Federal Circuit stated that: "[n]o overlap happens unless the violations occur at the same time." *Id.* at 1369-70. According to *Wyeth*, an applicant can be entitled to both A and B delays because no B delay occurs before the 3-year pendency date. Thus, there can be no overlap for A delays occurring before the 3-year pendency date.

The PTO's Old Calculation Deprived the Applicant of 148 Days of PTA

The PTO calculated 350 days of PTA for the instant '259 patent. As illustrated below, the correct calculation under *Wyeth* is 498 days. A copy of the prosecution history, downloaded from the PTO's PAIR database is attached as Exhibit A.

(a) A Delay

(i) The instant application was filed on November 11, 2003. The PTO mailed a Requirement for Restriction on March 14, 2006. The PTO Action was 425 days beyond 14 months from the filing date, resulting in a 425 day A delay.

(b) B Delay

The '066 application was filed on November 11, 2003. The Patent Issue Date was April 10, 2007. This resulted in a B delay of 148 days as follows. Three years from November 11, 2003 is November 11, 2006. The interval between November 11, 2006 and the April 10, 2007 Issue Date is 148 days.

(c) Overlap

The overlap is the period of A delay extending beyond the 3-year pendency date into the B delay period. Here, there is no overlap.

(d) Non-overlapped PTO Delay

The A + B delay, excluding overlap, is $425 + 148 = 573$ days.

(e) Applicant Delays

(i) Applicant delay was 46 days for the period in excess of three months from the Response to Restriction filed April 14, 2006 to the Information Disclosure Statement (IDS) filed May 30, 2006.

(ii) Applicant delayed 29 days for the period in excess of three months from the IDS filed May 30, 2006 to the October 6, 2006 Response After Non-Final Rejection.

(iii) The total applicant delay was $46 + 29 = 75$ days.

PTA under *Wyeth*

The correct PTA is $573 - 75 = 498$ days.

Conclusion

As detailed above, the '259 patent should have been granted 498 days of PTA. The PTO, using the old, incorrect calculation method, granted 350 days of PTA. Thus, the applicant was deprived of 148 days of patent term adjustment it should have been accorded under the statute. The PTO has provided a means for patents issued before March 2, 2010 to have a recalculation of their PTA via a Request for Recalculation of Patent Term Adjustment in View of *Wyeth* (PTO/SB/131) as long as the patent was not issued more than 180 days before the Request was filed. No regulation provides for a recalculation of the PTA for patents falling under 35 U.S.C. § 154 but outside of the PTO's arbitrary date restrictions. This is an extraordinary and unjust result that can be remedied by a grant of this Petition to have the PTO to reset the clock and recalculate the PTA in the instant case and that the PTO recognize the additional PTA due this patent.

Please charge any shortage in fees due in connection with the filing of this paper,
including extension of time fees, to Deposit Account 500417 and please credit any excess fees to
such deposit account.

Respectfully submitted,


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EXHIBIT A

Transaction History



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10/714,066

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Transaction History

Date	Transaction Description
11-03-2008	Change in Power of Attorney (May Include Associate POA)
10-30-2008	Correspondence Address Change
10-23-2008	Correspondence Address Change
04-10-2007	Recordation of Patent Grant Mailed
03-21-2007	Issue Notification Mailed
04-10-2007	Patent Issue Date Used in PTA Calculation
03-14-2007	Dispatch to FDC
03-03-2007	Application Is Considered Ready for Issue
02-26-2007	Issue Fee Payment Verified
02-26-2007	Issue Fee Payment Received
12-01-2006	Mail Notice of Allowance
11-29-2006	Notice of Allowance Data Verification Completed
11-29-2006	Case Docketed to Examiner in GAU
05-30-2006	Information Disclosure Statement considered
10-17-2006	Date Forwarded to Examiner
10-06-2006	Response after Non-Final Action
10-06-2006	Request for Extension of Time - Granted
05-30-2006	Information Disclosure Statement (IDS) Filed
05-30-2006	Information Disclosure Statement (IDS) Filed
06-07-2006	Mail Non-Final Rejection
06-01-2006	Non-Final Rejection
04-21-2006	Date Forwarded to Examiner
04-14-2006	Response to Election / Restriction Filed
03-14-2006	Mail Restriction Requirement
03-13-2006	Requirement for Restriction / Election
12-22-2005	Miscellaneous Incoming Letter
02-24-2005	IFW TSS Processing by Tech Center Complete
02-24-2005	Case Docketed to Examiner in GAU
04-23-2004	Application Return from OIPE
04-23-2004	Application Return TO OIPE
04-23-2004	Application Dispatched from OIPE
04-23-2004	Application Is Now Complete
04-08-2004	Additional Application Filing Fees
04-08-2004	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applicant
02-12-2004	Notice Mailed--Application Incomplete--Filing Date Assigned
02-01-2004	Cleared by OIPE CSR
12-30-2003	IFW Scan & PACR Auto Security Review
11-13-2003	Initial Exam Team nn

If you need help:

- Call the Patent Electronic Business Center at (866) 217-9197 (toll free) or e-mail EBC@uspto.gov for specific questions about Patent Application Information Retrieval (PAIR).
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